Secretary for Health and Family Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Secretary for Health and Family Services based on the September 17, 2009 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	P & T Vote	Final Decisions (s)
Branded Products with Generic Components Require prior authorization for the following products: • IC400® • IC800® • Benziq®	**Passed** 8 For 0 Against 1 Abstention	The following products will require prior authorization • IC400® • IC800® • Benziq®
New Drugs to Market: Lamictal XR™ Place this product preferred in the PDL category titled: Anticonvulsants: Second Generation.	**Passed** 7 For 1 Against 1 Abstention	Lamictal XR™ will be placed preferred in the PDL category titled: Anticonvulsants: Second Generation.
New Drugs to Market: Multaq® Allow this product to pay as preferred until it can be reviewed at the next PTAC meeting when the Committee's Cardiologist is present.	**Passed** 9 for 0 Against	Multaq® will pay as preferred until it can be reviewed at the next PTAC meeting when the Committee's Cardiologist is present.
New Drugs to Market: Cetraxal™ Place this product non preferred in the PDL category titled: Otic: Quinolone Antibiotics.	**Passed** 9 For 0 Against	Cetraxal™ will be placed non preferred in the PDL category titled: Otic: Quinolone Antibiotics.
New Drugs to Market: BenzaClin CareKit® Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.	**Passed** 9 For 0 Against	BenzaClin CareKit® will be placed non preferred in the PDL category titled Dermatologics: Antibiotic Agents for Acne.
New Drugs to Market: Nucynta™ Place this product non preferred in the PDL category titled: Narcotics: Short-Acting.	**Passed** 9 For 0 Against	Nucynta™ will be placed non preferred in the PDL category titled: Narcotics: Short-Acting.

<table>
<tr><th>Description of Recommendation</th><th>P & T Vote</th><th>Final Decisions (s)</th></tr>
<tr><td><u>New Drugs to Market: Edluar®</u>
Place this product non preferred in the PDL category titled: Sedative Hypnotic Agents with the following clinical criteria:

Edluar® will be approved if one of the following criteria is met:
• Diagnosis of dysphagia via an ICD-9 Override, OR

<table><tr><th>Diagnosis</th><th>ICD-9 Code</th></tr><tr><td>dysphagia</td><td>787.2</td></tr><tr><td>dysphagia - functional, hyseterical, or nervous</td><td>300.11</td></tr><tr><td>dysphagia - psychogenic</td><td>306.4</td></tr><tr><td>dysphagia - sideropenic</td><td>280.8</td></tr><tr><td>dysphagia - spastica</td><td>530.5</td></tr></table>
• Trial and failure of 2 preferred sedative hypnotics, one of which must be zolpidem.</td><td>Passed
9 For
0 Against</td><td>Edluar® will be placed non preferred in the PDL category titled: Sedative Hypnotic Agents with the following clinical criteria:

Edluar® will be approved if one of the following criteria is met:
• Diagnosis of dysphagia via an ICD-9 Override, OR

<table><tr><th>Diagnosis</th><th>ICD-9 Code</th></tr><tr><td>dysphagia</td><td>787.2</td></tr><tr><td>dysphagia - functional, hyseterical, or nervous</td><td>300.11</td></tr><tr><td>dysphagia - psychogenic</td><td>306.4</td></tr><tr><td>dysphagia - sideropenic</td><td>280.8</td></tr><tr><td>dysphagia - spastica</td><td>530.5</td></tr></table>
• Trial and failure of 2 preferred sedative hypnotics, one of which must be zolpidem.</td></tr>
<tr><td><u>New Drugs to Market: Adcirca™</u>
Place this product non preferred in the PDL category titled: Agents for Pulmonary Hypertension with the following clinical criteria:

Adcirca™ will be approved if both of the following criteria are met:
• Diagnosis of pulmonary hypertension via an ICD-9 Override (416.0, 416.8), AND
• Trial and failure of sildenafil via a 90 day electronic look back.</td><td>Passed
9 For
0 Against</td><td>Adcirca™ will be placed non preferred in the PDL category titled: Agents for Pulmonary Hypertension with the following clinical criteria:

Adcirca™ will be approved if both of the following criteria are met:
• Diagnosis of pulmonary hypertension via an ICD-9 Override (416.0, 416.8), AND
• Trial and failure of sildenafil via a 90 day electronic look back.</td></tr>
<tr><td><u>New Drugs to Market: Acuvail™</u>
Place this product non preferred in the PDL category titled: Ophthalmic NSAIDs.</td><td>Passed
9 For
0 Against</td><td>Acuvail™ will be placed non preferred in the PDL category titled: Ophthalmic NSAIDs.</td></tr>
<tr><td><u>New Drugs to Market: Effient™</u>
Allow this product to pay as preferred until it can be reviewed at the next PTAC meeting when the Committee's Cardiologist is present.</td><td>Passed
9 For
0 Against</td><td>Effient™ will pay as preferred until it can be reviewed at the next PTAC meeting when the Committee's Cardiologist is present.</td></tr>
</table>

Description of Recommendation	P & T Vote	Final Decisions (s)
Protein Tyrosine Kinase Inhibitors 1. DMS to select preferred agent(s) based on economic evaluation; however, at least imatinib should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA via a 90 day electronic look back. 3. All agents in the category will have no higher than a tier 2 copay regardless of PDL status. 4. DMS to allow continuation of therapy for existing users of non preferred products via a 90 day look back. 5. For any new chemical entity in the Protein Tyrosine Kinase Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against	Selected Preferred Agent (s) Gleevec®
Ranexa® Clinical Criteria Ranexa® (ranolazine) will be approved if the patient has a history of one agent in any of the following drug classes within the past 90 days (unless ALL are contraindicated). • Beta Blocker • Nitrate • Calcium Channel Blocker	**Passed** 9 For 0 Against	Ranexa® (ranolazine) will be approved if the patient has a history of one agent in any of the following drug classes within the past 90 days (unless ALL are contraindicated). • Beta Blocker • Nitrate • Calcium Channel Blocker
Lidoderm® Clinical Criteria Lidoderm® will be approved if any one of the following criteria are met: • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • History of one agent in any of the following medication classes in the past 90 days: o Tricyclic antidepressant o Anticonvulsant o SNRI	**Passed** 9 For 0 Against	Lidoderm® will be approved if any one of the following criteria are met: • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • History of one agent in any of the following medication classes in the past 90 days: o Tricyclic antidepressant o Anticonvulsant o SNRI

Description of Recommendation	P & T Vote	Final Decisions (s)
Hepatitis C: Pegylated Interferons 1. Rename the category Hepatitis C: Interferons. 2. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa-2a and peginterferon alfa-2b should be preferred. 3. Agents not selected as preferred will be considered non preferred. 4. PDL selected agents will apply for any new courses of therapy only. 5. All agents in the category will have no higher than a tier 2 copay regardless of PDL status. 6. Place clinical prior authorization around the entire class to ensure appropriate utilization. 7. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against	Selected Preferred Agent (s) PEGASYS® PEGASYS® Convenience pack PEG-Intron™ PEG-Intron™ Redipen

Description of Recommendation	P & T Vote	Final Decisions (s)
Hepatitis C: Pegylated Interferons Clinical Criteria All preferred and non-preferred pegylated interferons will require a prior authorization after the initial 16 weeks of therapy. **After the initial 16 weeks of therapy pegylated interferons will be approved if:** 1. HCV RNA Assay results obtained prior to initiation of therapy **AND** 12 weeks after initiation of therapy must be provided. If the difference between the two assays is at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), **THEN** approve for duration of therapy as defined below. 2. If the assays were done **BUT** the difference between the two assays **WAS NOT** at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), **THEN** refer the request to a clinical pharmacist who will deny the request. 3. If there is any other valid medical reason why the patient should require this therapy, a clinical pharmacist may approve the request for the total length of therapy as listed below. ***LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT*** 1. Interferon alfacon-1 a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a OR 2b a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy	**Passed** 9 For 0 Against	All preferred and non-preferred pegylated interferons will require a prior authorization after the initial 16 weeks of therapy. **After the initial 16 weeks of therapy pegylated interferons will be approved if:** 1. HCV RNA Assay results obtained prior to initiation of therapy **AND** 12 weeks after initiation of therapy must be provided. If the difference between the two assays is at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), **THEN** approve for duration of therapy as defined below. 2. If the assays were done **BUT** the difference between the two assays **WAS NOT** at least a 2 logarithmic unit decrease (example: from 2,000,000 IU to 20,000 IU), **THEN** refer the request to a clinical pharmacist who will deny the request. 3. If there is any other valid medical reason why the patient should require this therapy, a clinical pharmacist may approve the request for the total length of therapy as listed below. ***LIMITATION ON LENGTH OF THERAPY IS BASED ON PRODUCT*** 1. Interferon alfacon-1 a. IFN naïve – 24 weeks total therapy b. INF relapse – 48 weeks total therapy 2. Peginterferon alfa-2a OR 2b a. Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy b. Genotype 2, 3 – 24 weeks total therapy

Description of Recommendation	P & T Vote	Final Decisions (s)
Hepatitis C: Ribavirins 1. DMS to select preferred agent (s) based on economic evaluation; however, at least ribavirin should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization. 5. For any new chemical entity in the Hepatitis C: Ribavirins class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against	Selected Preferred Agent (s) ribavirin Ribapak™ Ribasphere™
Hepatitis C: Ribavirins Clinical Criteria Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.	**Passed** 9 For 0 Against	Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.

Description of Recommendation	P & T Vote	Final Decisions (s)
Antihyperkinesis Agents 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one sort-acting, one intermediate-acting and one long-acting formulation of methylphenidate and dextroamphetamine as well as atomoxetine should be preferred. 2. Agents not selected as preferred will be considered non preferred and require trial and failure of one preferred product, preferred generics must be tried before multisource branded products will be approved. 3. Require appropriate ICD-9 on all prescriptions for agents within this class. 4. Continue to require prior authorization for modafinil and armodafinil to ensure utilization in FDA-approved indications only. 5. Place quantity limits on all agents based on the American Academy of Child and Adolescent Psychiatry and FDA-approved maximum recommended dose. 6. Allow only one agent at a time for an extended release product and one agent at a time for an immediate release product unless switching agents due to therapeutic failure. 7. Allow continuation of therapy for non preferred products via a 90 day look back. 8. For any new chemical entity in the Antihyperkinesis class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against	Selected Preferred Agent (s) dexmehtylphenidate IR dextroamphetamine IR dextroamphetamine ER methylphenidate IR methylphenidate SA/SR mixed amphetamine salts IR Adderall® XR DextroStat® Focalin™ XR Metadate® CD Metadate® ER Methylin® (tablets, chewable tablets) Methylin® ER Strattera® Vyvanse™

<table>
<tr><th>Description of Recommendation</th><th>P & T Vote</th><th>Final Decisions (s)</th></tr>
<tr>
<td><u>Antihyperkinesis Agents Clinical Criteria</u>
Diagnosis to Approve via an ICD-9 Override:

<table>
<tr><th><u>Diagnosis</u></th><th><u>ICD-9</u></th></tr>
<tr><td>Attention Deficit/Hyperreactivity Disorder (ADHD)</td><td>314.1
314.01
314.2
314.8
314.9</td></tr>
<tr><td>Attention Deficit Disorder (ADD)</td><td>314.00</td></tr>
<tr><td>Narcolepsy</td><td>347.00
347.01
347.11</td></tr>
<tr><td>Sleep apnea/hypoapnea syndrome</td><td>780.57
780.51
780.53</td></tr>
<tr><td>Shift work sleep disorder</td><td>307.45</td></tr>
</table>

**Agents may be approved for other diagnosis via the prior authorization process based on a review of the current literature by a clinical pharmacist.

Quantity Limits/Maximum Daily Dose
• Adderall® 60 mg per day
• Adderall® XR 60 mg per day
• Concerta® 108 mg per day
• Daytrana™ 30 mg per day
• Desoxyn® 25 mg per day
• Dexedrine® IR 60 mg per day
• Dexedrine® ER 60 mg per day
• dexmethylphenidate 50 mg per day
• dextroamphetamine IR 60 mg per day
• dextroamphetamine ER 60 mg per day
• DextroStat® 60 mg per day
• Focalin™ 50 mg per day
• Focalin™ XR 50 mg per day
• Metadate® CD 100 mg per day
• Metadate® ER 100 mg per day
• methamphetamine 25 mg per day
• Methylin® 100 mg per day
• Methylin® ER 100 mg per day</td>
<td>Passed
9 For
0 Against</td>
<td>Antihyperkinesis Agents will have the following prior authorization criteria:
Diagnosis to Approve via an ICD-9 Override:

<table>
<tr><th><u>Diagnosis</u></th><th><u>ICD-9</u></th></tr>
<tr><td>Attention Deficit/Hyperreactivity Disorder (ADHD)</td><td>314.1
314.01
314.2
314.8
314.9</td></tr>
<tr><td>Attention Deficit Disorder (ADD)</td><td>314.00</td></tr>
<tr><td>Narcolepsy</td><td>347.00
347.01
347.11</td></tr>
<tr><td>Sleep apnea/hypoapnea syndrome</td><td>780.57
780.51
780.53</td></tr>
<tr><td>Shift work sleep disorder</td><td>307.45</td></tr>
</table>

**Agents may be approved for other diagnosis via the prior authorization process based on a review of the current literature by a clinical pharmacist.

Quantity Limits/Maximum Daily Dose
• Adderall® 60 mg per day
• Adderall® XR 60 mg per day
• Concerta® 108 mg per day
• Daytrana™ 30 mg per day
• Desoxyn® 25 mg per day
• Dexedrine® IR 60 mg per day
• Dexedrine® ER 60 mg per day
• dexmethylphenidate 50 mg per day
• dextroamphetamine IR 60 mg per day
• dextroamphetamine ER 60 mg per day
• DextroStat® 60 mg per day
• Focalin™ 50 mg per day
• Focalin™ XR 50 mg per day
• Metadate® CD 100 mg per day
• Metadate® ER 100 mg per day
• methamphetamine 25 mg per day
• Methylin® 100 mg per day
• Methylin® ER 100 mg per day</td>
</tr>
</table>

• methylphenidate IR 100 mg per day • methylphenidate SR 100 mg per day • mixed amphetamine salt IR 60 mg per day • mixed Amphetamine salt ER 60 mg per day • Nuvigil® 150 mg per day • Procentra™ 60 mg per day • Provigil® 400 mg per day • Ritalin® 100 mg per day • Ritalin® LA 100 mg per day • Ritalin® SR 100 mg per day • Strattera® 100 mg per day • Vyvanse™ 70 mg per day Therapeutic Duplication Prior authorization will be required for more than one long-acting (Adderall® XR, Concerta®, Daytrana™, Desoxyn®, Dexedrine® ER, dextroamphetamine ER, Metadate® CD, Metadate® ER, methamphetamine, Focalin™ XR, Methylin® ER, methylphenidate SR, mixed amphetamine salt ER, Procentra™, Ritalin® LA, Ritalin® SR, Strattera®, Vyvanse™), or more than one short-acting (Adderall®, amphetamine salt combo, Dexedrine® IR, dexmethylphenidate, dextroamphetamine IR, DextroStat®, Focalin™, Methylin®, methylphenidate, mixed amphetamine salt IR, Ritalin®) stimulant at a time.		• methylphenidate IR 100 mg per day • methylphenidate SR 100 mg per day • mixed amphetamine salt IR 60 mg per day • mixed Amphetamine salt ER 60 mg per day • Nuvigil® 150 mg per day • Procentra™ 60 mg per day • Provigil® 400 mg per day • Ritalin® 100 mg per day • Ritalin® LA 100 mg per day • Ritalin® SR 100 mg per day • Strattera® 100 mg per day • Vyvanse™ 70 mg per day Therapeutic Duplication Prior authorization will be required for more than one long-acting (Adderall® XR, Concerta®, Daytrana™, Desoxyn®, Dexedrine® ER, dextroamphetamine ER, Metadate® CD, Metadate® ER, methamphetamine, Focalin™ XR, Methylin® ER, methylphenidate SR, mixed amphetamine salt ER, Procentra™, Ritalin® LA, Ritalin® SR, Strattera®, Vyvanse™), or more than one short-acting (Adderall®, amphetamine salt combo, Dexedrine® IR, dexmethylphenidate, dextroamphetamine IR, DextroStat®, Focalin™, Methylin®, methylphenidate, mixed amphetamine salt IR, Ritalin®) stimulant at a time.

<table>
<tr><th>Description of Recommendation</th><th>P & T Vote</th><th>Final Decisions (s)</th></tr>
<tr><td><u>Antihyperkinesis Agents, Special Formulations Clinical Criteria</u>
Daytrana™, Methylin® Solution, Methylin® Chewable Tabs, or Procentra™ will be approved if either of the following criteria are met:
Trial and failure of one preferred product, which must be the same chemical as the requested medication; OR
Inability to swallow/tolerate PO/whole tablets/capsules
For Daytrana™ , inability to swallow/tolerate PO medications; OR
For Methylin® Solution, Methylin® Chewable Tabs, or Procentra™, inability to swallow tablets or capsules whole.</td><td>Passed
9 For
0 Against</td><td>Daytrana™, Methylin® Solution, Methylin® Chewable Tabs, or Procentra™ will be approved if either of the following criteria are met:
Trial and failure of one preferred product, which must be the same chemical as the requested medication; OR
Inability to swallow/tolerate PO/whole tablets/capsules
For Daytrana™ , inability to swallow/tolerate PO medications; OR
For Methylin® Solution, Methylin® Chewable Tabs, or Procentra™, inability to swallow tablets or capsules whole.</td></tr>
<tr><td><u>Provigil® / Nuvigil® Clinical Criteria</u>
Provigil® (modafinil) / Nuvigil® (armodafinil) will be approved if both of the following criteria are met:
One of the following approvable diagnosis (via ICD-9 override):
<table><tr><td>Narcolepsy</td><td>347.00</td></tr><tr><td></td><td>347.01</td></tr><tr><td></td><td>347.11</td></tr><tr><td>Sleep apnea/hypoapnea syndrome</td><td>780.57</td></tr><tr><td></td><td>780.51</td></tr><tr><td></td><td>780.53</td></tr><tr><td>Shift work sleep disorder</td><td>307.45</td></tr></table>
For Nuvigil® (armodafinil) ONLY, trial and failure of Provigil® (modafinil) via a 90 day look back</td><td>Passed
9 For
0 Against</td><td>Provigil® (modafinil) / Nuvigil® (armodafinil) will be approved if both of the following criteria are met:
One of the following approvable diagnosis (via ICD-9 override):
<table><tr><td>Narcolepsy</td><td>347.00</td></tr><tr><td></td><td>347.01</td></tr><tr><td></td><td>347.11</td></tr><tr><td>Sleep apnea/hypoapnea syndrome</td><td>780.57</td></tr><tr><td></td><td>780.51</td></tr><tr><td></td><td>780.53</td></tr><tr><td>Shift work sleep disorder</td><td>307.45</td></tr></table>
For Nuvigil® (armodafinil) ONLY, trial and failure of Provigil® (modafinil) via a 90 day look back</td></tr>
</table>

Description of Recommendation	P & T Vote	Final Decisions (s)
Corticosteroids, Intranasal 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which must be fluticasone furoate, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue to maintain quantity limits based on maximum daily dose. 4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&T Advisory Committee.	**Passed** 6 For 2 Against 1 Abstention	Selected Preferred Agent (s) fluticasone propionate Nasonex Veramyst®